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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,880	04/22/2002	Alexander Sher	113308-005	6145
24573	7590	12/28/2004	EXAMINER	
BELL, BOYD & LLOYD, LLC PO BOX 1135 CHICAGO, IL 60690-1135			PRATT, HELEN F	
			ART UNIT	PAPER NUMBER
			1761	

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/914,880	Applicant(s) SHER ET AL. JR	
	Examiner Helen F. Pratt	Art Unit 1761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-8,11-13,16-19,21,23 and 25-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 29-31 is/are allowed.
- 6) ☒ Claim(s) 1,3-8,11-13,16-19,23 and 25-28 is/are rejected.
- 7) ☐ Claim(s) 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 21 is redundant with claim 30.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-9, 11-13, 16-19, 23, 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Medical research (673,063) in view of Barani et al. and Kaishi.

Medical research discloses that it is known to make an iron-protein hydrolysate out of egg albumin (egg white) (page 2, lines 85-95). Claim 1 differs from the reference in the particular molecular weight (mw). However, nothing is seen and nothing has been shown that molecular weights within the claimed range are not used in the composition of the combined references. The independent claims contains the limitation that the molecular weight is in the range of about 2,000 to 6,000. However, nothing is seen that the reference to MR does not contain these weights because the protein is hydrolyzed to polypeptones and the like and unconverted proteins (page 2,

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lines 10-16). It would have been expected that since the claimed process has been disclosed that the claimed molecular weights would have been present. In addition, Barani et al. disclose a composition which contains an iron-protein hydrolysate complex made from ferrous ions and hydrolyzed egg white protein (abstract and page 3, lines 5-13, lines 25-30, and page 4, lines 25-32 and page 5, lines 4-8). Kashi (XP-000914255) discloses that it is known to make an iron and egg-white albumin hydrolyzate (abstract, last 5 lines). In addition, nothing critical is seen in the higher molecular weights, as 500 had previously been claimed. Therefore, it would have been obvious to make an iron-protein hydrolysate complex with various molecular weights.

Claim 3 requires that the egg protein is hydrolyzed with a microbial protease. Kaishi discloses that the hydrolysis was done using *Bacillus subtilis*, which is a microbial protease, which would produce a microbial protease hydrolysate (abstract). Therefore, it would have been obvious to make a microbial hydrolysate as claimed.

Claims 4-5 require particular proteases. However, as one protease has been disclosed which makes a hydrolyzate, it would have been within the skill of the ordinary worker to use other protease, absent anything new or unobvious being produced. Therefore, it would have been obvious to use other proteases to make the claimed composition.

Claim 6 requires that the complex contain particular amounts of ferrous ions and claim 7 that it is stable at a neutral pH, but disassociates at a pH below 4. It is seen at this time that the above composition from the various references do contain the claimed amount of ferrous ions. Barani et al. disclose that the iron content is 11%, which is a little

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more than the claimed amount (page 6, lines 24-25). No patentable distinction is seen in the use of 10% and 11 % at this time. Therefore, it would have been obvious to use particular amounts of iron in the composition as shown by Barani et al. Medical research discloses a pH of amount 3-6 (page 2, lines 25-30). It is not known whether the composition disassociates at a pH of below 3. Since the claimed composition has been shown at the right pH, it is seen that it would have disassociated at below a pH of 3. . Therefore, it would have been obvious to use the teachings of the references to Barani et al. and Kaishi in the composition and process MR because these references are to various aspects of hydrolyzed proteins.

Therefore, it would have been obvious to make a product as claimed as shown by the above references.

The limitations of claims 8, 11-13, 16-18 have been disclosed above and are obvious for those reasons.

Claim 19 further requires that the iron protein hydrolysate complex is a sterilized liquid. Nothing new is seen in sterilizing liquids, which is within the skill of the ordinary worker. Therefore, it would have been obvious to sterilize the claimed composition.

Claim 23 is to a beverage powder containing lipids. However, fortified beverage powders are well known as is fat in food composition. The reference to Barani discloses that it is known to use iron in foods (page 2, 17-21). Powders are disclosed in page 5, lines 25-29). Therefore, it would have been obvious to use the claimed composition in a powder.

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The limitations as to the process have been disclosed by Medical Research as in claims 25-28, who uses an enzymatic agent to digest proteins which can be egg white (albumin (page 2, lines 25-56, page 1, lines 80-85, page 2, lines 25-30, lines 50-55)). Therefore, it would have been obvious to make a composition as claimed.

Allowable Subject Matter

Claim 21 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Claims 29-31 are allowed.

ARGUMENTS

Applicant's arguments filed 4-26-04 have been fully considered but they are not persuasive. Applicants argue that Applicants invention is defined by a particular molecular weight. Nothing has been shown that the hydrolyzed protein of MR does not disclose the claimed molecular weight, as in polypeptones, peptides and unconverted proteins (page 2, lines 12-20 and lines 30-34).

Applicants argue that MR is to preparing complexes of free amino acid and iron. However, the reference is not limited to free amino acids as discussed above. The specification on page 6, lines 3-5 does not show any comparison between the degree of hydrolyzation of egg white to define over the references.

It is not seen that a laundry list of materials can be used in MR, but various proteins in a group of 6. The composition of the reference is said to have been more effective than previous iron compositions and uses less of the composition to administer iron.

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Applicants argue that Barani is to acylation and hydrolysis is optional. However, the reference discloses acylated hydrolysis or the other (page 5, lines 4-6). The method steps of Barani are not considered in a composition claim, and have not been excluded from the claimed method.

Applicants argue as to Kaishi that that it is to showing the antioxidant levels of hydrolysates. Even so, this does not exclude the fact that it is known how to make an iron-egg-white albumin hydrolyzate and is not limited to the most active peptide.

It is seen that the claimed product and process has been disclosed by the combined references, absent a showing that the claimed weight of the hydrolyzed proteins of MR are not within the claimed range.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen F. Pratt whose telephone number is 571-272-1404. The examiner can normally be reached on Monday to Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Milton Cano, can be reached on 571-272-1398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hp 12-23-04

H. Pratt
HELEN PRATT
PRIMARY EXAMINER